REMARKS

Entry of the foregoing, re-examination and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. § 1.111, and in light of the remarks which follow, are respectfully requested.

Claim 2 has been amended to further improve its form which does not narrow the scope of the claim. Claims 26 and 55 were previously canceled.

Upon entry of the Amendment, claims 1-25, 27-54 and 56-67 will be all the claims pending in the application.

I. Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-25, 27-38, 41-44, 47-54 and 56-63 were rejected under 35 U.S.C. § 112, first paragraph.

Applicants respectfully traverse the rejection for the reasons set forth in the Amendment filed March 14, 2007 and the following additional reasons.

The written description requirement under 35 U.S.C. § 112, first paragraph requires that the disclosure describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429,1438 (Fed. Cir. 2003).

The Examiner appears to consider that the specification does not provide written description for the terms "peripheral nervous system stimulant," "physiologically acceptable vehicle" and "unattractive sensation" recited in the present claims.

Applicants respectfully submit that the specification sufficiently describes the above terms and as such one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Specifically, the present claims recite that the unattractive sensation is at least one selected from the group consisting of stinging, pins and needles, itching, pruritus, hotness and pulling. These specific unattractive sensations are explicitly described in paragraph [0057] of the specification. The Examiner does not dispute that the meanings of these terms are clear to one skilled in the art.

Turning to the term "a peripheral nervous system stimulant," the specification describes in paragraph [0051] that "[t]he peripheral nervous system stimulant is an agent which induces a sensorial response linked to the deployment of sensitive skin nerves whose ends emerge within the stratum corneum." The specification continues in paragraph [0052] that "[t]he peripheral nervous system stimulant is a substance capable of inducing an unattractive sensation when applied topically to the skin. Moreover, the agent is capable of inducing release of substance P and/or CGRP when applied topically to the skin." These descriptions clearly describe the nature and characteristics of a "peripheral nervous system stimulant," and as much one skilled in the art can reasonably understand the meaning thereof.

Turning to the term "physiologically acceptable vehicle," the specification describes in paragraph [0049] that "[a] physiologically acceptable vehicle is a vehicle which is compatible with the skin, mucosae, nails and hair. Moreover, this vehicle is appropriate for the application of the peripheral nervous system stimulant and permits ready bioavailability of the stimulant following topical application to the skin, without this vehicle itself being a peripheral nervous system stimulant." These descriptions clearly describe the nature and

characteristics of a "physiologically acceptable vehicle," and as much one skilled in the art can reasonably understand the meaning thereof.

Furthermore, the terms "peripheral nervous system stimulant," "physiologically acceptable vehicle" and "unattractive sensation" are known in the art and the meanings thereof are understood by a person skilled in the art. Applicants should not be required to describe in detail in the specification information which is well known in the art. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

Moreover, various claims recite specific peripheral nervous system stimulants or physiologically acceptable vehicles, as appeared in the specification. Specifically, claim 13 recites that "the peripheral nervous system stimulant is an agent which induces a sensorial response linked to the deployment of sensitive skin nerves;" claim 14 recites that "the peripheral nervous system stimulant is a substance that can induce an unattractive sensation when applied topically to the skin and can induce release of at least one of substance P and CGRP when applied topically to the skin;" claim 15 recites that the peripheral nervous system stimulant is a natural capsaicinoid, a synthetic capsaicinoid, a lactic acid, a glycolic acid, an ethanol at a concentration greater than 50%, or a mustard oil; claim 16 recites that the peripheral nervous system stimulant is selected from the group consisting of a capsaicin, a homocapsaicin, a homodihydrocapsaicin, and a nordihydrocapsaicin; claims 17 and 20 recite that the peripheral nervous system stimulant is capsaicin; claim 37 recites that a stimulant is a capsaicinoid or a mustard oil; claim 52 recites that the peripheral nervous system stimulant is a natural capsaicinoid, a synthetic capsaicinoid, a synthetic extract or a plant extract; claim 53 recites that the capsaicinoid is a capsaicin, a homocapsaicin, a homodihydrocapsaicin, a nordihydrocapsaicin, or a dihydrocapsaicin; claim 54 recites that the capsaicinoid is a

capsaicin; claims 20-25, 37, 38 and 48-51 are limited to an aqueous solution and/or an aqueous-alcoholic solution. For at least these reasons, Applicants traverse the rejection of claims 13-17, 20-25, 37, 38 and 48-54 additionally.

In view of the above, Applicants respectfully submit that the specification provides sufficient written description of the invention recited in the present claims, and thus the rejection should be withdrawn.

II. Response to Rejections under 35 U.S.C. § 103(a)

a. Claims 1-17, 20-25, 27-38, 41-44 and 48-54 were rejected under 35 U.S.C. § 103(a) as being obvious over Robinson et al., *Contact Dermatitis*, "Evaluation of a quantitative clinical method for assessment of sensory skin irritation," 45:205-213, 2001.

Applicants respectfully traverse the rejection for the reasons set forth in the Amendment filed March 14, 2007 and the following additional reasons.

Robinson et al. relates to the development of better methods for predictive testing and risk assessment for dermatological products and, thus, for standardized tests for evaluating irritation risks of new ingredients or products.

One part of the study described in Robinson et al. consists of (i) questioning subjects on the intensity of recalled/imagined sensations when testing these subjects with the product; and then (ii) identifying the degree of correlation between self-perceived reactivity to recall/imagined skin stimuli and actual measured chemosensory responses.

The conclusion of this part of the study is that no consistency exists between the intensity of the recalled/imagined sensations and the actual measured chemosensory reactivity after applying a product (see page 210 and Fig. 7).

Concerning another part of the study in Robinson et al. considerable variability between individual subjects was found when testing with capsaicine, even across the range of skin sensations described.

In view of the above, one of ordinary skill in the art would rather have been taught away from using capsaicine to elaborate a method to classify one population, e.g., concerned with sensitive skin. Indeed, variability between individual subjects has to be avoided to achieve a reliable method to evaluate the level of skin neurosensitivity.

Moreover, there is no description or suggestion in Robinson et al. that capsaicine, in a low concentration as defined in the present claims, would be useful in classifying one population concerned with sensitive skin.

In this regard, as noted by the Examiner, Robinson et al. uses 100-10,000 μM capsaicin in 80% ethanol, which does not fall within the presently claimed low concentration, such as 1×10^{-6}% and 1×10^{-4}% by weight, of a peripheral nervous system stimulant relative to the total weight of the composition. Moreover, there is no indication in Robinson et al. that such low concentrations would be useful for cosmetic diagnosis allowing identification of subjects with sensitive skin from others, without any pain and without giving rise to adverse side effects.

Furthermore, the presently recited concentration of peripheral nervous system stimulant is important in evaluating the level of skin neurosensitivity. This is because when using more concentrated solutions, the test may cause an individual who does not have a sensitive skin to feel unpleasant sensation, thereby leading to false positive results. On the other hand, as described in the attached article, which is partially authored by the present inventors, using relatively low concentrations of capsaicine, such as those defined in the

present claims, can allow the detection of sensitivity, which is not dependent upon subject's appreciation.

Moreover, the use of low concentrations of peripheral nervous system stimulant, such as capsaicine, as recited in the present claims, allows use of a lower concentration of physiologically acceptable vehicle, such as ethanol, and as such the test can be applied on the face of an individual.

In view of the foregoing, Applicants respectfully submit that the present claims are not obvious over Robinson et al., and thus the rejection should be withdrawn.

b. Claims 1-17, 20-25, 27-38, 41-44 and 48-54 [Claims 56-63, sic] were rejected under 35 U.S.C. § 103(a) as being obvious over Robinson et al. in view of U.S. Patent No. 6,139,850 to Hahn et al.

Applicants respectfully traverse the rejection for the reasons set forth in the Amendment filed March 14, 2007, the reasons set forth above, and the following additional reasons.

The Examiner's position is that "the claimed invention is obvious over the teachings of Robinson et al. alone, and, this is also rejected as being obvious over Hahn et al. in combination with Robinson et al."

Applicants respectfully disagree. First, in the previous Office Action dated September 14, 2006, claims 1-17, 20-38, 41-44 and 48-55 were rejected over Robinson et al. and claims 56-63 were rejected over Robinson et al. in view of Hahn et al. (see pages 9 and 12 of the Office Action). It should be noted that the rejection of claims 1-17, 20-38, 41-44 and 48-55 over Robinson et al. did not include claims 56-63. Further, claims 56-63 were only rejected over Robinson et al. and Hahn et al. That is, claims 56-63 were considered by

the Examiner to contain features which are not disclosed or suggested by Robinson et al. and thus are patentable over Robinson et al. alone.

Moreover, if Hahn et al. was not actually relied upon in the rejection, as stated in the present Office Action, the rejection "over Robinson et al. and further in view of Hahn et al." would be no different from a rejection over Robinson et al. alone, thereby rendering the citation of Hahn et al. meaningless.

Applicants respectfully request that the Examiner clarify this rejection by specifying the rejected claims and the relied-upon references.

III. Response to Obviousness-Type Double Patenting Rejection

Claims 3, 5-9 and 16 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 57 of copending U.S. Patent Application No. 10/674,491.

While not conceding the propriety of this rejection, Applicants submit herewith a Terminal Disclaimer to expedite prosecution. The filing of a Terminal Disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). The court indicated that the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection."

In view of the above, the Examiner is respectfully requested to reconsider and withdraw the provisional nonstatutory obviousness-type double patenting rejection.

IV. Conclusion

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned at (202) 452-7932 at his earliest convenience.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: September 28, 2007 By: _____

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